

Atty. Dkt. No. 025217-0121

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Nora Yat Knork Chew et al.
Title: TOPICAL DELIVERY OF ANTIFUNGAL AGENTS
Appl. No.: 10/644,085
Filing Date: 08/20/2003
Examiner: Not yet assigned
Art Unit: 3761

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial Nos. 09/125,436 filed December 18, 1998 and 09/910,780 filed July 24, 2001. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the submitted documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

14 April 2004

By

S. A. Bent

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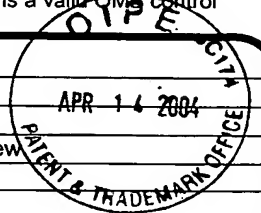
Stephen A. Bent

Attorney for Applicant

Registration No. 29,768

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: April 14, 2004 <i>(use as many sheets as necessary)</i>		Application Number	10/644,085
		Filing Date	08/20/2003
		First Named Inventor	Nora Yat Knork Chew
		Group Art Unit	3761
		Examiner Name	Not yet assigned
Sheet	1	of	3
		Attorney Docket Number	025217-0121



U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,082,866		WONG et al.	1/1992	
		5,256,647		MINASKANIAN et al.	10/1993	
		5,034,386		PECK et al.	7/1991	
		4,704,406		STANISIAUS et al.	11/1987	
		5,804,168		MURAD	09/1998	
		3,989,816		RAJADHYAKSHA	11/1976	
		4,299,826		LUEDDERS	11/1981	
		4,440,777		ZUPAN	04/1984	
		4,557,934		COOPER	12/1985	
		4,820,724		NIMNI	04/1989	
		4,954,487		COOPER et al.	09/1990	
		5,036,100		DEBOECK et al.	07/1991	
		5,122,519		RITTER	06/1992	
		5,487,898		LU et al.	01/1996	
		6,299,900	B1	REED et al.	10/2001	
		4,663,157		BROCK	05/1987	
		4,699,779		PALINCZAR	10/1987	
		5,449,519		WOLF et al.	09/1995	
		5,573,754		KULKARNI et al.	11/1996	
		4,946,671		BISSETT et al.	08/1990	
		4,310,511		HOLICK	01/1982	
		4,938,951		LEUNG et al.	07/1990	
		5,679,374		FRANCHON et al.	10/1997	
		5,082,656		HUI et al.	1/1992	
		4,077,407		ALZA CORPORATION	03/07/1978	
		3,598,122		ALZA CORPORATION	08/10/1971	
		3,598,123		ALZA CORPORATION	8/10/1971	
		3,742,951		ALZA CORPORATION	07/03/1973	
		3,814,097		IMPERIAL CHEMICAL INDUSTRIES LTD.	06/04/1974	
		3,921,636		ALZA CORPORATION	11/25/1975	
		3,993,072		ALZA CORPORATION	11/23/1976	
		3,993,073		ALZA CORPORATION	11/23/1976	
		3,996,934		ALZA CORPORATION	12/14/1976	
		4,031,894		ALZA CORPORATION	06/28/1977	
		4,060,084		ALZA CORPORATION	11/29/1977	
		4,069,307		ALZA CORPORATION	01/17/1978	
		4,201,211		ALZA CORPORATION	05/06/1980	
		4,230,105		MERCK & CO., INC.	10/28/1980	
		4,292,299		TEIJIN LIMITED	09/29/1981	

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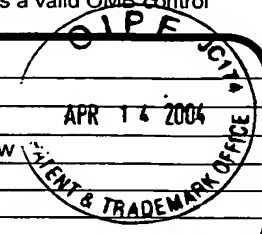
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⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet	3	of	3
		Attorney Docket Number	025217-0121



NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 6
		Physicians' Desk Reference (49 Ed.) 1995, pp. 1151-1152, Medical Economics Company, Inc. Montvale N.J.	
		Khabir AHMED "US Physicians and WHO plead for aid to Afghanistan", The Lancet, Vol. 357, 6/2001, pp. 1769.	
		William M. CHAMBERS et al., "Terbinafine-induced hepatic dysfunction", European Journal of Gastroenterology & Hepatology 2001, Vol. 13, No. 9, pp. 1115-1118.	
		D.T. ROBERTS, "Onychomycosis: current treatment and future challenges", British Journal of Dermatology, 1999, 141 (Suppl. 56):1-4.	
		A. TOSTI et al., "Relapses of Onychomycosis after Successful Treatment with Systemic Antifungals: A Three Year Follow Up", Dermatology 1998: 197: 162-166.	
		Daniele DEBRUYNE et al., "Pharmacokinetics of Antifungal Agents in Onychomycoses", Clin. Pharmacokinet 2001: 40(6): 441-472.	
		Claus SEEBACHER et al., "A Multicenter, Open-Label Study of the Efficacy and Safety of Ciclopirox Nail Lacquer Solution 8% for the Treatment of Onychomycosis in Patients with Diabetes", Efficacy and Safety of Ciclopirox, Volume 68, August 2001, pp. 17-22.	
		Roderick James HAY et al., "Risk/benefit ratio of modern antifungal therapy: Focus on hepatic reactions", Journal of the American Academy of Dermatology, July 1993, pp. S50-S54.	
		D.T. ROBERTS, "Oral Terbinafine (Lamisil®) in the Treatment of Fungal Infections of the Skin and Nails", Dermatology 1997, 194 (suppl 1):37-39.	
		Harvey LEMONT et al., "Terbinafine-Associated Taste Disturbance with Normal Taste Threshold Scores", Journal of the American Podiatric Medical Association, pp. 540-541.	
		M. ZAUG et al., "Amorolfine in the treatment of onychomycoses and dermatomycoses (an overview)", Clinical and Experimental Dermatology 1992, 17 (Suppl. 1): 61-70.	
		R.J. HAY et al., "Tioconazole nail solution—an open study of its efficacy in onychomycosis", Clinical and Experimental Dermatology (1985) 10, 111-115.	
		Barrie C. FINNIN et al., "Transdermal Penetration Enhancers: Applications, Limitations, and Potential", Journal of Pharmaceutical Sciences, Vol. 88, No. 10, 10/1999, pp. 955-958.	
		Aditya K. GUPTA et al., "Ciclopirox nail lacquer solution 8% in the 21 st century" J. AM. ACAD DERMATOL, 10/2000, pp. S96-S102.	

Examiner Signature		Date Considered	
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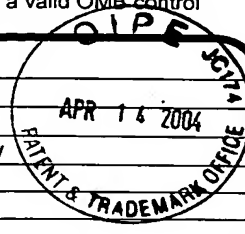
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Sheet	2	of	3		



U.S. PATENT DOCUMENTS

U.S. Patent Document		
4,292,303	KEY PHARMACEUTICALS, INC.	09/29/1981
5,323,769	CYGNUS THERAPEUTIC SYSTEMS	06/28/1994
5,023,085	PFIZER INC.	06/11/1991
5,474,783	NOVEN PHARMACEUTICALS INC.	12/12/1995
4,941,880	BIOJECT INC.	07/17/1990

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			DE 43 34 553			04/1995		
			JP 61-268631			11/1986		
			WO 92/19271			11/1992		
			AU 30258/89			09/1989		
			AU 49984/1990			09/1989		
			AU 91413/91			06/1992		
			WO 96/30000			10/1996		
			EP 189 861			08/1986		
			EP 0 552 405	A1	Lintec Corporation	07/1993		
			EP 0 608 322	B1	Deckner et al.	07/1998		

NON PATENT LITERATURE DOCUMENTS

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		R.J. FELDMANN et al., "Percutaneous Penetration of 14C Hydrocortisone in Man", Arch Derm, Vol. 94:649-651, (1966).	
		M.F. COLDMAN et al., "Enhancement of Percutaneous Absorption by the Use of Volatile: Nonvolatile Systems and Vehicles", Journal of Pharmaceutical Sciences, Vol. 58(9):1098-1102, (1969).	
		P.P. BHATT et al., "Finite Dose Transport of Drugs in Liquid Formulations Through Stratum Corneum: Analytical Solution to a Diffusion Model", International Journal of Pharmaceutics, Elsevier Science Publishers B.V. Vol. 50:197-203, (1989).	
		NIMNI, U.S. Patent Number 4,820,742, Internet: WWW.PATENTS.IBM.COM/FEI-BIN/ANY2HTM Document "Dual Phase Solvent Carrier System", pp. 3, 4 & 6 out of 7 pages.	
		BUCKS et al., "Percutaneous Absorption of Hydroquinone in Humans: Effect of 1-Dodecylazacloheptan-2-One (Azone) and the 2 Ethylhexyl Ester of 4-(Dimethylamino) Benzoic Acid (Escalol 507), Journal of Toxicology and Environmental Health, 24:279-289 (1988).	

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